

ELABORATIONS

News and Issues for Washington's Clinical Laboratories

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Washington's Laboratory Complaint Process

by Linda Parisi, DOH/LQA

On May 31, 2006 the General Accounting Office (GAO) released a report on the federal CLIA program. One of GAO's recommendations was that laboratorians should be knowledgeable about how they can file complaints against laboratories. Two accrediting organizations, CAP and COLA, have required that posters be displayed in their laboratories to insure that lab workers know how to file complaints.

The Laboratory Quality Assurance (LQA) office investigates all relevant complaints concerning laboratories that are licensed under the Medical Test Site (MTS) law. LQA requests that complaints be made in writing outlining the specific details of the issue and mailed to the LQA Office, 1610 NE 150th Street, Shoreline, WA 98155. The complainant can also make an initial inquiry by calling LQA at (206) 418-5418 or the Department of Health (DOH) Complaint Hotline at (800) 633-6828.

LQA does not investigate complaints about personnel issues, OSHA/WISHA concerns, billing fraud and abuse, etc. LQA does not investigate complaints about physicians, nurses, or any other health care professionals. If the complaint is about a person who provides medical care or services, contact the Health Professions Quality Assurance of the Department of Health at (360) 236-4700. If you are unsure whether the complaint is against the facility or a person, please submit the complaint to us anyway, and we will route it to the appropriate office for review.

LQA requests that complaints be made in writing outlining the specific details of the issue that cannot or has not been able to be resolved internally by the laboratory administra-

tion. The identity of the complainant is not required; however, if the investigation results in legal action, LQA cannot guarantee the anonymity of the complainant in those proceedings. If the complainant prefers anonymity, no name or identifying information will be recorded. Upon receipt of a complaint, LQA's complaint coordinator will determine the priority level of the complaint. The priority level determines the extent of the investigation. The investigation may be (a) an unannounced, on-site inspection; (b) an investigation by telephone, requesting records and documentation; (c) a follow-up at the next survey; or (d) referral to another federal or state agency or the laboratory's accrediting organization. If the MTS rule does not apply and the complaint cannot be referred to another agency, LQA's complaint coordinator will determine whether to contact the facility and inform them of the complaint based upon the nature of the complaint. If the complaint is substantiated, the surveyor will write a Statement of Deficiency (SOD) and require the facility to complete corrective action within sixty (60) days. The

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Practice Guidelines

The following practice guidelines have been developed by the Clinical Laboratory Advisory Council. They can be accessed at the following website:
www.doh.wa.gov/lqa.htm

Anemia	Lipid Screening
ANA	PAP Smear
Bioterrorism Event Mgmt	Point-of-Care Testing
Bleeding Disorders	PSA
Chlamydia	Rash Illness
Diabetes	Red Cell Transfusion
Group A Strep Pharyngitis	Renal Disease
Group B Streptococcus	STD
Hepatitis	Thyroid
HIV	Tuberculosis
Infectious Diarrhea	Urinalysis
Intestinal Parasites	Wellness

National Provider Identifier (NPI) Information

Article provided by Noridian Administrative Services.

Background: The NPI will replace the provider identification numbers that providers use today in the HIPAA standard transactions that they conduct with health plans. Those transactions include the electronic claim, eligibility inquiry and response, claim status inquiry and response, payment and remittance advice, prior authorization/referral, and coordination of benefits transactions.

Providers who conduct any of those electronic transactions must have their NPIs and be ready to use them to identify themselves, and possibly other providers, in those transactions before May 23, 2007. This is less than a year from now. Some health plans might be ready to accept NPIs much earlier than next May. The health plans with whom you do business will inform you as to when you may begin using your NPIs in these electronic transactions.

- CMS reminds health care providers that they need to obtain their National Provider Identifiers (NPIs).
- Today, approximately 530,000 providers who are Individuals and Organizations have obtained their NPIs.
- Providers can obtain NPIs by:
 - Going to the web at <https://nppes.cms.hhs.gov> and filling out their application online.
 - Obtaining a paper application form, filling it out, and

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NOTE: Letters to the editor may be published unless specified otherwise by the author.

Website addresses:

DOH home page: <http://www.doh.wa.gov>
LQA home page: <http://www.doh.wa.gov/lqa.htm>
PHL home page:
<http://www.doh.wa.gov/EHSPHL/PHL/default.htm>

mailing it to the NPI Enumerator. They can obtain the paper application form (CMS-10114) by downloading it from www.cms.hhs.gov/forms or by calling the NPI Enumerator at (800)-465-3203 and requesting a copy.

- Submitting an application through Electronic File Interchange (EFI). EFI allows an approved organization, after obtaining the permission of a provider, to send the provider's NPI application data in an electronic file.
- Medicare organization providers are required by the NPI Final Rule to determine if they have subparts and if those subparts should have their own NPIs. Many enrolled Medicare providers are actually subparts of other enrolled Medicare providers who are their "parents." In January 2006, Medicare posted a paper about the subpart concept and its effect on Medicare organization providers (downloadable from www.cms.hhs.gov/NationalProvIdentStand, click on "Medicare NPI Implementation" on the left). Medicare encourages its enrolled organization providers to become familiar with the contents of that paper if they have not already done so, and to use that paper in making decisions concerning subparts and their assignment of NPIs.
- Providers and suppliers are required to include their NPI on the 04/2006 version of the CMS-855 Medicare enrollment application when they apply to enroll in Medicare.
- Medicare will accept either the Medicare provider number (the legacy provider number) or the NPI and the Medicare provider number (both numbers) on the claims it receives from providers through October 2, 2006.
- Beginning October 2, 2006 and continuing through May 22, 2007, Medicare will accept the NPI or the Medicare provider number (legacy provider number) on the claims it receives from providers. If there is any issue with the provider's NPI and no Medicare provider number is included on the claim, the provider might not be paid. Therefore, Medicare strongly recommends that providers, clearinghouses, and billing services continue to submit the Medicare provider number (the legacy provider number) as a secondary identifier until May 22, 2007.
- CMS has posted many documents related to the NPI, including Medicare's timetable for implementation of the NPI, on its NPI web page: www.cms.hhs.gov/NationalProvIdentStand. Visit this website and become familiar with the NPI and how it will be used, if you have not already done so.
- We encourage all organizations and associations to inform their members about the need to obtain, test, and use the NPI.

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WellnessScreeningGuideLine

Washington State Clinical Laboratory Advisory Council
Originally published: July 1998 Reviewed: October 2000 Revised: June 2006

Screening laboratory/testing augments a physical examination in two ways: 1) test results may provide an impetus for life-style changes that can reduce the risk of developing a life-threatening condition, and 2) testing prior to the development of symptoms may help to detect disease in an early/treatable stage. The following are recommended testing for men and women in different age groups.

FOR EDUCATIONAL PURPOSES ONLY
The individual clinician is in the best position to determine which tests are most appropriate for a particular patient.

Conditions	Testing for Adolescents (13-19)	Testing for Adults (20-29)	Testing for Adults (30-49)	Testing for Adults 50 and Up
Cervical Cancer*	AAFP: Pap testing every three years who are or have been sexually active. ¹ ACS: Annual Pap testing at the onset of sexual activity or age 18, whichever is earlier. ²	AAFP: Pap testing every three years who are or have been sexually active. ¹ ACS: Annual Pap testing at the onset of sexual activity. ²	AAFP: Pap testing every three years who are or have been sexually active. ¹ ACS: Annual Pap testing until at least after three negative tests. ²	AAFP: Pap testing every three years who are or have been sexually active. ¹ ACPM: Screening may be discontinued at age 65 if the following criteria are met: the woman has been regularly screened, has had two satisfactory smears, and has had no abnormal smears within the previous nine years. For all women over age 65 who have not been previously screened, three normal annual smears should be documented prior to discontinuation of screening. ³ ACS: Annual Pap testing until at least three negative tests. ² USPSTF: The USPSTF recommends against routinely screening women older than age 65 for cervical cancer if they have had adequate recent screening with normal Pap smears and are not otherwise at high risk for cervical cancer. ⁴
Chlamydia Infections*	CDC: Annual testing for sexually-active females under 20 years of age or women ages 20 and older with one or more chlamydia risk factors. ⁵ USPSTF: Screening testing for all sexually-active women younger than age 25 or younger, and all women, pregnant or not, who may be at risk. ⁶	CDC: Annual testing for sexually-active females under 20 years of age or women ages 20 and older with one or more chlamydia risk factors. ⁵ USPSTF: Screening testing for all sexually-active women younger than 25, all asymptomatic pregnant women age 25 or younger, and all women, pregnant or not, who may be at risk. ⁶	CDC: Annual screening for women age 20 and older with one or more risk factors, all women with infection of the cervix, and all pregnant women. ⁵	CDC: Annual screening for women age 20 and older with one or more risk factors, all women with infection of the cervix, and all pregnant women. ⁵
Hyper-cholesterolemia*	NA	NCEP: Everyone 20 years old and older should have their blood cholesterol measured at least once every 5 years. More frequent testing is recommended if known risk factors are present. ⁷	NCEP: Lipid profile testing including total cholesterol, HDL-cholesterol, LDL-cholesterol, and triglycerides is recommended every five years, or more frequently based on "borderline" results or the presence of risk factors. ⁷	NCEP: Lipid profile testing including total cholesterol, HDL-cholesterol, LDL-cholesterol, and triglycerides is recommended every five years, or more frequently based on "borderline" results or the presence of risk factors. ⁷
Iron Overload	NA	CAP: Begin screening at age 20. Perform transferrin saturation testing (TS: iron/TIBC) and follow-up with ferritin if elevated. Persons with elevated TS and normal ferritin initially may be followed with ferritin testing at 1 to 2 year intervals. ⁸	CAP: Perform transferrin saturation testing (TS: iron/TIBC) and follow-up with ferritin if elevated. Persons with elevated TS and normal ferritin initially may be followed with ferritin testing at 1 to 2 year intervals. Many hemochromatosis homozygotes have symptoms and signs of illness by age 40. ⁹	NA

*For additional information, please see specific CLAC practice guideline at www.doh.wa.gov/hsqafsl/ga_practice_guidelines.htm

NOTE: See reverse side for key to abbreviations.

(Over)

Basic Blood Cell Morphology Training Class

COURSE DATE: September 14, 2006. Registration begins at 8:00; class starts at 8:15 am and ends at about 3:00 pm.

HOW TO REGISTER: Complete the registration form and mail to the Department of Health, PHL Training Program or FAX to (206) 418-5445. A confirmation packet will be sent to you by mail. The packet will contain your registration confirmation, payment instructions and a map to the training location. Please do not send money with your registration form.

COURSE CONTENT:

The lecture section of this one-day course will cover the following subjects:

- Maturation and cell function of red and white blood cells.
- Examination of red and white cell morphology using Kodachrome slides.

In the laboratory section of this one-day course the following activities will be conducted:

- Practice making adequate smears.
- Hands-on microscopic examination of normal and abnormal blood differentials.

WHO SHOULD ATTEND: This basic course is designed for laboratory assistants, physicians assistants, nurses and other health care providers responsible for making and evaluating blood differential smears in physician offices.

TUITION:

\$115.00 (Before September 7, 2006)

\$125.00 (After September 7, 2006)

CONTINUING EDUCATION UNITS:

Students will receive 0.6 CEUs for completion of this course. Applicants must plan to attend the entire workshop to receive CEUs. Accreditation provided through the State of California Department of Health Services, Office of Laboratory Field Services, 2151 Berkley Way- Annex 12, Berkley, California 94704-1011.

LOCATION: The course will be held at the Public Health Laboratories, 1610 NE 150th Street, Shoreline, Washington 98155. A map and driving directions will be sent to each registered student. All breaks, laboratory materials, manuals, and use of equipment are included. Students are responsible for their own transportation, meals, and lodging.

REGISTRATION FORM:

Basic Blood Cell Morphology Training Class Registration Form

Name: _____

Employer: _____

Employer Address: _____

City: _____ State: _____ Zip: _____

Work Phone: _____ FAX: _____

E-mail: _____ Message Phone: _____

HOW TO REGISTER: Complete the registration form and mail to the **Department of Health Training Program, 1610 NE 150th Street, PO Box 550501, Shoreline, WA 98155-9701**, fax to **(206) 418-5445** or e-mail to **phl.training@doh.wa.gov**. A registration form is available at our web site: **www.doh.wa.gov/ehsphl/phl/training/train.htm**. **DO NOT SEND MONEY WITH YOUR REGISTRATION FORM.**

Basic Urine Sediments Training Class

COURSE DATE: **October 12, 2006.** Registration begins at 8:00; class starts at 8:15 am and ends at about 3:30 pm.

HOW TO REGISTER: Complete the registration form and mail to the Department of Health, PHL Training Program or FAX to (206) 418-5445. A confirmation packet will be sent to you by mail. The packet will contain your registration confirmation, payment instructions and a map to the training location. Please do not send money with your registration form.

COURSE CONTENT:

At the completion of this course, participants will have gained proficiency in recognizing sediments in urine. These training sessions emphasize recognizing urine sediments. Participants will perform actual microscopic examination of urine sediments and review reference slides. Also included in the course will be pertinent lectures regarding quality assurance, quality control, correlation of results, collection of adequate specimens, and basic kidney physiology.

WHO SHOULD ATTEND: This training session is designed for persons examining urine sediments in hospital laboratories, physician office labs, clinics, and other testing entities.

PREREQUISITE: Student must be competent in use of a microscope.

TUITION:

\$115.00 (Before October 4, 2006)

\$125.00 (After October 4, 2006)

CONTINUING EDUCATION UNITS:

Students will receive 0.6 CEUs for completion of this course. Applicants must plan to attend the entire workshop to receive CEUs. Accreditation provided through the State of California Department of Health Services, Office of Laboratory Field Services, 2151 Berkley Way-Annex 12, Berkley, California 94704-1011.

LOCATION: The course will be held at the Public Health Laboratories, 1610 NE 150th Street, Shoreline, Washington 98155. A map and driving directions will be sent to each registered student. All breaks, laboratory materials, manuals, and use of equipment are included. Students are responsible for their own transportation, meals, and lodging.

REGISTRATION FORM:

Basic Urine Sediments Training Class Registration Form

Name: _____

Employer: _____

Employer Address: _____

City: _____ State: _____ Zip: _____

Work Phone: _____ FAX: _____

E-mail: _____ Message Phone: _____

HOW TO REGISTER: Complete the registration form and mail to the **Department of Health Training Program, 1610 NE 150th Street, PO Box 550501, Shoreline, WA 98155-9701**, fax to **(206) 418-5445** or e-mail to **phl.training@doh.wa.gov**. A registration form is available at our web site: **www.doh.wa.gov/ehsphl/phl/training/train.htm**. **DO NOT SEND MONEY WITH YOUR REGISTRATION FORM.**

WA Laboratory Complaint Process, continued from page 1

laboratory will be billed for the complaint investigation if substantiated. If there are deficiencies that constitute an immediate and serious threat to the patient's health and safety, the surveyor will require that testing be suspended. When all documentation has been completed, the surveyor will notify the complainant of the outcome of the investigation either by phone or letter if this is requested.

NPI Information, continued from page 2

NPI Application TIPS:

Applying Online

- Complete a hard copy version of the application before attempting online data entry.
- You will NOT be able to save your work if you quit before you have completed the application form.
- Print each page as you complete the application to keep a record for your file.
- Use the application's navigation buttons, NEXT or PREVIOUS.
- Do NOT use the browser's buttons, BACK and FORWARD.
- If you have a problem with the system and cannot continue, wait 20 minutes before logging on again.

Paper and Web Application Tips

- Remember to select an entity type:
 - Entity type 1**, health care providers who are individuals, need to complete sections 2A, 3, 4A, and 5.
 - Entity type 2**, health care providers who are organizations or subparts, need to complete sections 2B, 3, 4B, and 5.
- When you enter your Medicaid number in section 3.c., list the state that assigned the number.
- Post office boxes may not be entered as practice location addresses.
- To view your information online, you will need to apply for a web User ID and password in addition to the NPI number.

Paper Application Tips

- Do not staple the application pages together.
- Remember to print legibly or type your application.
- Include an original signature of the health care provider and a telephone number on the application. Blue ink is best.
- Do not send a photocopy of the signature or a stamped signature. The name in the signature must match the name of the provider.

Laboratory-Based Practice Guidelines

To address inappropriate or unnecessary use of laboratory testing services, the Clinical Laboratory Advisory Council decided to establish a process for developing practice guidelines for clinical laboratory testing. The guidelines are for educational purposes only.

The intent of the guidelines is to help laboratorians answer questions they may get from clinicians on appropriate test ordering. The guidelines will also be useful to clinicians as a review of a typical test-ordering pattern for asymptomatic patients. The guidelines are a compilation of existing data, not original work by the Council. For the format, the Council elected to summarize existing information into simple, easy-to-use flow charts. Once a test has been identified by the Council as a candidate for a guideline, a Council workgroup is formed to develop a proposed guideline. The draft guideline is reviewed by the entire Council, members of the state's laboratory community and appropriate medical professional societies. Comments from the reviewers are evaluated by the Council workgroup and incorporated into the final document. The finalized guideline is disseminated to all clinical laboratories and other interested parties through this newsletter.

FOR EDUCATIONAL PURPOSES ONLY!

The guidelines should be used strictly as guidelines. The individual clinician is in the best position to determine which tests are most appropriate for a particular patient.

Guidelines developed by the Council that have been previously published in ELABORATIONS are listed in the box on page 1 of this newsletter. This issue of ELABORATIONS contains the Wellness Screening Guideline.

13th Annual Clinical Laboratory Conference

November 13, 2006
8:00 a.m. - 4:30 p.m.

Seattle Doubletree Hotel at SeaTac
International Airport

If you have not received a copy of the program by the end of September, contact Leonard Kargacin:
phone: (206) 418-5416,
e-mail: leonard.kargacin@doh.wa.gov

The program will be available from the LQA website:
http://www.doh.wa.gov/hsqa/fsl/lqa_updates.htm.

Calendar of Events

PHL Training Classes:
(<http://www.doh.wa.gov/ehsphl/phl/training/train.htm>)

A Basic Course in Blood Cell Morphology
September 14 Shoreline

A Basic Course in Urine Sediments
October 12 Shoreline

Northwest Medical Laboratory Symposium
October 18-21 Portland

12th Annual Clinical Laboratory Conference
November 13 Seattle

2006 WSSCLS/NWSSAMT Spring Meeting
April 26-28, 2007 Tri-Cities

Contact information for the events listed above can be found on page 2. The Calendar of Events is a list of upcoming conferences, deadlines, and other dates of interest to the clinical laboratory community. If you have events that you would like to have included, please mail them to ELABORATIONS at the address on page 2. Information must be received at least one month before the scheduled event. The editor reserves the right to make final decisions on inclusion.